K002402

AUG 31 2000

ATTACHMENT K
SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Mitek Products is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Mitek Products choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects..."

The summary regarding the adverse health effects of the proposed **VAPR™ TC Electrode for use with the VAPR™ II Electrosurgical System** is as follows:

Trade Name: VAPR™ TC Electrode for use with VAPR™ II Electrosurgical System

Sponsor: Mitek Products
249 Vanderbilt Avenue
Norwood, MA 02062
Registration: 1221934

Device Generic Name: Electrosurgical Generator and electrode

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices: K963783 - Mitek VAPR™ Electrosurgical System
K974022 – Mitek VAPR™ T Thermal Electrode
K964071 – Oratec Interventions, Inc. ORA-50 ElectroThermal System

All of the devices mentioned above have been determined substantially equivalent by FDA.

Device Description: The VAPR™ II Electrosurgical System is an electrosurgical system consisting of an electrosurgical generator, footswitch, and handpiece with integral genertor connector cable.

The VAPR™ TC electrode described in this 510(k) is a sterile, disposable electrode designed for use with the Mitek VAPR™ II Electrosurigal System.

Safety and Performance: This submission is a Special 510(k): Device Modification as described in FDA's Guidance Document entitled, "The New 510(k) Paradigm – Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of the 510(k), Mitek has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Mitek's subcontractor Design Control and Risk Analysis procedures, and the results of validation testing (performance testing) for the device modification.

Conclusion: Based on the Indications for Use, technological characteristics and safety and performance testing, the **VAPR™ TC Electrode** when used with the **VAPR™ II Electrosurgical System** have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Ms. Mary P. LeGraw
Manager, Regulatory Affairs
Mitek Products
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K002402
Trade Name: VAPR™ TC Electrode for use with VAPR™ II Electrosurgical System
Regulatory Class: II
Product Code: HRX, GEI
Dated: August 4, 2000
Received: August 7, 2000

Dear Ms. Legraw:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002402

Device Name: VAPR™ TC Electrode for use with VAPR™ II Electrosurgical System

Indications for Use for the VAPR™ TC Electrode:

The Mitek VAPR™ II Electrosurgical System, when used with a VAPR™ TC Electrode, is intended for coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist.

Indications for Use for the VAPR™ II Electrosurgical System:

The Mitek VAPR™ II Electrosurgical System, when used with a VAPR™ Electrode, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, ankle, elbow and wrist.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____

Donna R. Bochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002402